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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/783,783

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Alan R. Klenk

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09/13/2006

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EXAMINER

Yabut, Diane D

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/783,783

Applicant(s)

KLENK ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/20/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/19/05; 5/2/05</u>   | 6) <input checked="" type="checkbox"/> Other: <u>4/26/04</u>                |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statements (IDS) submitted on 26 April 2004, 2 May 2005, and 19 August 2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Claim Objections***

2. Claim 20 is objected to because of the following informalities: On line 2 of Claim 29 it reads "the coil" and should instead read --a coil--. Appropriate correction is required.

3. Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 26 recites "comprising a coil having a proximal end releasably engaging the loading portion and a distal end releasably engaging the tissue piercing structure" when the same limitation is recited in lines 2-5 of Claim 1.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **20050119675**) in view of Figures 6-10, page 7, paragraphs 108 and 112.

Claims 1 and 10: Adams et al. discloses delivering an elongate body **1122** having a proximal end and a distal end to the patent foramen ovale, and a coil **1100** releasably engaged with the elongate body, advancing the coil through the septa **304**, **306** of the patent foramen ovale, and releasing the coil from the elongate body, wherein the coil when released contracts to pinch the septum primum and septum secundum together (Figures 34A-34B, page, 14, paragraph 175). Adams et al. discloses the claimed invention except for the elongate body having a tissue piercing structure at its distal end, advancing the tissue piercing structure through the septum secundum and then through the septum primum, and withdrawing the tissue piercing structure from the septa of the patent foramen ovale.

Another embodiment of Adams et al. teaches a tissue piercing structure **320** at its distal end, advancing the tissue piercing structure through the septa **304**, **306** of the patent foramen ovale, and withdrawing the tissue piercing structure from the septum secundum and then through the septum primum, in order to quickly advance through

Art Unit: 3734

the septa and draw the septum secundum and septum primum toward another (Figures 6-10, page 7, paragraphs 108 and 112). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue piercing structure to advance and withdraw from the septa of the patent foramen ovale, as taught by another embodiment of Adams et al., to Adams et al. in order to quickly advance the closure device through the septa and to facilitate drawing the septum secundum and the septum primum together.

Claim 2: Adams et al. discloses the elongate body **1122** having an opening near its distal end (Figure 34A-34B).

Claim 9: Adams et al. teaches an elongate body being delivered through an outer catheter **308** (Figure 10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an elongate body being delivered through an outer catheter, as taught by another embodiment of Adams et al., to Adams et al., in order to protect surrounding tissues of the coil closure device during delivery to the patent foramen ovale, prior to engaging the septa together and since it was known in the art that catheters are commonly used for delivery of devices.

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **20050119675**) and Figures 6-10, page 7, paragraphs 108 and 112 of Adams et al., as applied to Claim 2 above, and further in view of **Johnson et al.** (U.S. Pat. No. **6,485,504**).

Art Unit: 3734

Claims 3 and 4: Adams et al. discloses the claimed device, including the coil being advanced through the patent foramen ovale, except for the coil having a distal end that releasably engages the opening in the elongate body near its distal end and a loading portion that releasably engages a proximal end of the coil, the coil being advanced while being engaged with both the loading portion and the opening near the distal end of the elongate body to axially elongate and radially reduce the coil.

Johnson et al. teaches a coil **100** with a distal end that releasably engages the opening **116** in the elongate body **108** near its distal end and a loading portion (the proximal end of **108**) that releasably engages a proximal end of the coil, the coil being advanced while being engaged with both the loading portion and the opening near the distal end of the elongate body to axially elongate and radially reduce the coil, in order for the coil to fit into the hole in the tissue (Figures 24-26 and col. 19, lines 9-32). It would have been obvious to one of ordinary skill in the art to provide a coil that is releasably engaged at both proximal and distal ends to a loading portion and an opening in the distal end of the elongate body, respectively, to axially elongate and radially reduce the coil, as taught by Johnson et al., to the combined embodiments of Adams et al. in order to narrow the coil in diameter to fit the hole in the tissue.

7. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **20050119675**) and Figures 6-10, page 7, paragraphs 108 and 112 of Adams et al., as applied to Claim 1 above, and further in view of **Laufer et al.** (U.S. Pub. No. **20040193194**).

Art Unit: 3734

Claims 5-7: Adams et al. discloses the claimed device, including delivering an elongate body to the patent foramen ovale, except for delivering a loading collar with the elongate body, the loading collar releasably engaging a proximal end of the coil, the elongate body configured to be rotatable and axially slideable relative to the loading collar.

Laufer et al. teaches delivering a loading collar **864** with the elongate body **881a** or **881b**, the loading collar releasably engaging a proximal end of the coil, the elongate body configured to be rotatable and axially slideable relative to the loading collar. (Figures 14A-14B and page 6, paragraphs 114-115). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading collar with the elongate body that is releasably engaged to the proximal end of the coil, as taught by Laufer et al., to the combined embodiments of Adams et al. in order to protect and secure the proximal end of the coil and advance it towards the tissue while avoiding the need for another instrument to release the coil from the proximal end into the tissue.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **20050119675**) and Figures 6-10, page 7, paragraphs 108 and 112 of Adams et al. and **Laufer et al.** (U.S. Pub. No. **20040193194**), as applied to Claim 7 above, in further view of **Johnson et al.** (U.S. Pat. No. **6,485,504**).

Claim 8: Adams et al. and Johnson et al. disclose the claimed device except for the elongate body being advance relative to the loading collar prior to advancing the coil to axially elongate the coil. See paragraph 6 for discussion of Claims 3 and 4 that recite this limitation using Johnson et al.

Art Unit: 3734

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **20050119675**) and Figures 6-10, page 7, paragraphs 108 and 112 of Adams et al., as applied to Claim 1 above, and further in view of **Pierson, III** (U.S. Pat. No. **6,663,633**).

Claim 11: Adams et al. discloses the claimed device, including the coil being a first coil and releasing the first coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, except for advancing the tissue piercing structure and a second coil releasably engaged with the elongate body through the septa of the patent foramen ovale at a location adjacent to the first coil and releasing the second coil from the elongate body and withdrawing the tissue piercing structure from the septa of the patent foramen ovale, wherein the second coil when released contracts to pinch the septum primum and the septum secundum together. In other words, Adams et al. essentially discloses the claimed device except for using a second coil adjacent to the first coil to draw the septa together.

Pierson, III teaches a first coil **12** and an adjacent second coil **12'** that draw the two ends of the tissue **90** together (Figure 1E). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second coil to the septa of the patent foramen ovale, as taught by Pierson, III, to the combined embodiments of Adams et al. in order to provide a more secure closure of the septum primum and the septum secundum by covering more surface area of the tissue.



Art Unit: 3734

10. Claims 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Pub. No. **20050119675**) and Figures 6-10, page 7, paragraphs 108 and 112 of Adams et al., in view of **Pierson, III** (U.S. Pat. No. **6,663,633**).

Claims 12-19: The combined embodiments of Adams et al. disclose a method of closing a patent foramen ovale having a septum primum and septum secundum and advancing a coil over a single elongate body at least partially through the septa of the patent foramen ovale using a tissue piercing structure on the distal end of the elongate body to secure the septum primum and septum secundum together, including advancing the coil first through either of the septum primum or septum secundum and then through the other septum (page 14, paragraph 175) so that both ends of the coil are attached to opposing septa and atria, except for using a plurality of coils, or three coils, advanced sequentially through a single catheter. See explanation for Claims 1, 2, 9, and 10 in paragraph 5 above.

Pierson, III teaches advancing a plurality of coils **12** and **12'** to draw opposing sides of tissue **90** together through a single catheter (Figures 1A-1E and col. 7, lines 61-67, col. 8, lines 1-17). See paragraph 9 for discussion of Claim 11 that recites this limitation using Pierson, III. It would have been obvious to one of ordinary skill in the art to provide the advancement of a plurality of coils through a single catheter, as taught by Pierson, III, to Adams et al. in order to facilitate the subsequent advancement of the second coil after the first coil without having to reload or use another device. It also would have been obvious to one of ordinary skill in the art to provide three coils to

Art Unit: 3734

Adams et al. since it was known in the art that the use of multiple fasteners covers more surface area and strengthens the binding force and closure of tissue.

11. Claims 20-21 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Johnson et al.** (U.S. Pat. No. **6,485,504**) in view of **Laufer et al.** (U.S. Pub. No. **20040193194**).

Claims 20 and 26: Johnson et al. discloses the claimed device, including a loading portion (the proximal end of **108**) adapted to releasably engage a distal end of a coil **100** and a distal structure adapted to releasably engage a distal end of the coil, wherein the loading portion holds the coil relative to the piercing structure to axially elongate and radially reduce the coil (Figures 24-26), except for using a tissue piercing structure.

Laufer et al. teaches a hollow tissue piercing structure **881b** configured to releasably engage with the distal end of the coil and has a loading portion **864** adapted to releasably engage a proximal end of the coil (Figure 14B and page 6, 114). It would have been obvious to one of ordinary skill in the art to provide a tissue piercing structure, as taught by Laufer et al., to Johnson et al., since it was known in the art that tissue piercing structures are commonly used in delivery of fasteners, clips, and anchors into tissue.

Claim 21: Johnson et al. discloses the claimed device except for the loading portion being integral with the tissue piercing structure.

Laufer et al. teaches a loading portion **864** being integral with the tissue piercing structure **881b** (Figure 14B). It would have been obvious to provide a loading portion being integral with a tissue piercing structure, as taught by Laufer et al., to Johnson et

Art Unit: 3734

al., since it was known in the art that that in order to properly deliver and align a closure device with a piercing structure to a tissue, its loading portion should be integral with the piercing structure so as to puncture the tissue perpendicularly, which would quickly advance the piercing structure through the tissue with minimal damage or tearing.

Claims 24 and 25: Johnson et al. discloses the claimed device except for a loading collar, and the tissue piercing device being moveable relative to the loading collar, and the tissue piercing structure being provided on an elongate body extending through the loading collar.

Laufer et al. discloses a loading collar **864** with the tissue piercing structure **881b** provided on an elongate body having a proximal end and a distal end, the elongate body extending through the loading collar (Figure 14B). See explanation for Claims 20 and 26 in paragraph 12 above.

12. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Johnson et al.** (U.S. Pat. No. **6,485,504**) and **Laufer et al.** (U.S. Pub. No. **20040193194**), as applied to Claim 21 above, and in further view of **Kay** (U.S. Patent No. **5,662,683**).

Claim 22: Johnson et al. and Laufer et al. disclose the claimed device except for the loading portion comprising a slot adapted to receive the proximal end of the coil.

Kay teaches a loading portion **30** comprising a slot **44** adapted to receive the proximal end of the coil **10**, which enables the surgeon to apply a force to the coil (Figure 7, col. 4, lines 49-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a loading portion comprising a slot, as taught by

Art Unit: 3734

Kay, to Johnson et al. and Laufer et al. in order for the surgeon to apply a force to the coil, which facilitates its delivery to tissue.

Claim 23: Laufer et al. discloses a tissue piercing structure **881b** including an opening adapted to releasably engage the distal end of the coil (Figure 14B and page 6, paragraph 114).

13. Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Johnson et al.** (U.S. Pat. No. **6,485,504**) and **Laufer et al.** (U.S. Pub. No. **20040193194**), as applied to Claim 26 above, and further in view of **Bolduc et al.** (U.S. Patent No. **5,582,616**).

Claims 27-28: Johnson et al. and Laufer et al. disclose the claimed device except for the proximal and distal end of the coil comprising a tang that extends into a diameter defined by the coil.

Bolduc et al. teaches a proximal end of a coil **110** comprising a tang **122** that extends into a diameter defined by a coil in order to connect it to a delivery mechanism (Figure 3). Although Bolduc et al. does not disclose a similar tang on the distal end of the coil, it would have been obvious to one of ordinary skill in the art to provide a tang on either or both ends of the coil in order to attach the coil to a delivery device so that it can be secured before being attached to a tissue.

14. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Johnson et al.** (U.S. Pat. No. **6,485,504**) and **Laufer et al.** (U.S. Pub. No. **20040193194**), as applied to Claim 20 above, and further in view of **Adams et al.** (U.S. Pub. No. **20050119675**).

Art Unit: 3734

Claim 29: Johnson et al. and Laufer et al. disclose the claimed device except for the coil being sized to extend through a septum primum and a septum secundum of a patent foramen ovale.

Adams et al. teaches a coil being sized to extend through a septum primum and a septum secundum of a patent foramen ovale (Figures 34A-34B and page 14, paragraph 175). It would have been obvious to one of ordinary skill in the art to provide a coil sized to extend through a septum primum and a septum secundum of a patent foramen ovale since it was known in the art that a closure device is needed for the septa of the patent foramen ovale since blood clots can pass through the opening and cause a stroke.

15. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Johnson et al.** (U.S. Pat. No. **6,485,504**) and **Laufer et al.** (U.S. Pub. No. **20040193194**), as applied to Claim 20 above, and further in view of **Pierson, III** (U.S. Pat. No. **6,663,633**).

Claim 30: Johnson et al. and Laufer et al. disclose the claimed device except for the loading portion being adapted to releasably engage a plurality of coils.

Pierson, III teaches a loading portion **10** being adapted to releasably engage a plurality of coils (Figures 1A-1E and col. 7, lines 61-67, col. 8, lines 1-17).

See paragraphs 9-10 for discussion of Claims 11-10 that recite this limitation using Pierson, III.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY



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